IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

Doris Raub,	§	
	§	
Plaintiff,	§	CIVIL ACTION NO. 7:11-cv-032
	§	
vs.	§	
	§	
MATRIXX INITIATIVES, INC., ZICAM, L.L.C., and BOTANICAL LABORATORIES, INC. ,	§	
	§	
Defendants.	§	

MOTION TO EXCLUDE TESTIMONY OF STEVEN PIKE, M.D. (FEDERAL RULE OF EVIDENCE 702)

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MOTION TO EXCLUDE TESTIMONY OF STEVEN PIKE, M.D. (FEDERAL RULE OF EVIDENCE 702)

Defendants Matrixx Initiatives, Inc. and Zicam, L.L.C. (collectively "Matrixx") respectfully submit this Motion to Exclude the Testimony of Stephen Pike M.D., plaintiff's sole causation expert, pursuant to Federal Rule of Evidence 702.

INTRODUCTION AND SUMMARY OF ARGUMENT

This motion seeks the exclusion of unreliable and irrelevant expert opinion. To assess general causation, Dr. Steven Pike ("Pike") relies entirely on improper, unsupported extrapolations, ipse dixits, and bare assumptions to conclude that the complete and permanent smell loss alleged by Plaintiff Doris Raub ("Raub") resulted from her use of Zicam Cold Remedy Oral Mist ("ZCROM").

Pike's general causation opinion is based on a subjective hypothesis developed entirely for litigation and unsupported by any scientific test or study. His theory that ordinary oral ingestion of a zinc gluconate-containing oral mist can topically deliver a toxic dose of zinc ions to the olfactory epithelium located at the roof of the nose and produce permanent anosmia has never been tested; has never been peer-reviewed and published, and therefore never subjected to the scrutiny of the scientific and medical communities; not only is it not generally accepted in the scientific community, it flies in the face of an unbroken string of clinical studies of oral zinc gluconate administration which produced not a single episode of persistent smell loss; and there is no quantifiable error rate associated with his entirely subjective and theoretical methodology – the potential for error is infinite. His proffered testimony ignores several serious analytical gaps interrupting the journey from the data to his opinion that oral zinc causes permanent anosmia. For these reasons and others detailed below, Pike's general causation testimony lacks the intellectual and scientific rigor ordinarily applied to causal investigations in the fields of toxicology and epidemiology, significantly deviates from the applicable scientific method, and lacks the overall reliability necessary to permit its admission into evidence. In the words of Rule

702, his opinion is not based on sufficient facts or data, and it is not the product of a reliable application of reliable scientific methods.

Dr. Pike's specific causation opinion fares even worse. Having improperly "ruled in" ZCROM as a potential cause of Raub's permanent anosmia, itself fatal to his specific causation conclusion, Pike – who never examined Raub – simply leaps to the conclusion that it was also *the* cause of her condition, without considering any of the obvious, well-established alternative causes for her anosmia. Raub used ZCROM to treat a condition – her cold – which is a well-established and ubiquitous cause of permanent anosmia. She was also 76 years old when she developed anosmia, squarely within an age group at very high risk for age-induced anosmia – a fact not even mentioned by Pike in his report. By failing to address, much less rule out, the cold and Raub's age or any of the other two hundred or so causes of anosmia, Dr. Pike's specific causation opinion harbors a large, unbridged analytical gap. Indeed, it is a prototypical *ipse dixit* opinion. And it too lacks the required basis in sufficient facts or data and a reliable application of reliable scientific methods.

Dr. Pike's general and specific causation opinions are also irrelevant under Rule 702 and ultimately unhelpful to the trier of fact, because they lack the requisite "fit" measured by applicable state law, Texas substantive causation standards. Rule 702 requires the expert's testimony to have a valid scientific connection to the pertinent inquiry, that inquiry being defined by the disputed facts and the requirements of state law. To have probative value as evidence of causation under Texas law, a causation opinion must be supported by two well-designed epidemiological studies demonstrating that the risk of the medical condition (permanent anosmia) is more than doubled by the exposure characteristic (*i.e.*, ingestion of an oral zinc gluconate mist or ZCROM). Dr. Pike purports to evaluate the statistical risk of anosmia from ZCROM use based on an FDA anecdotal report database, even if this could be considered a "study" it is not a proper, controlled epidemiological study, it is not an accepted and validated type of study, and it is not peer-reviewed and published. Nor is it reliable and scientifically

valid. Nor is it replicated – it is an isolated "study." It is insufficient under Texas law and therefore lacks the requisite fit, as well as reliability, under Rule 702.

For these reasons, Dr. Pike's opinion is not based on reliable scientific methodology, nor is it based on reliable and sufficient facts or data, nor does it assist the trier of fact. This is junk science that has no place in the courtroom. It should be excluded.

FACTUAL AND PROCEDURAL BACKGROUND

A. The Facts and Allegations Surrounding Raub's Loss of Sense of Smell

In the interest of brevity and efficiency, Defendants refer to and incorporate by reference the factual background set forth in their pending Motion for Summary Judgment, Document No. 16 filed June 4, 2012, pages 4-8.

B. Procedural History

Defendants refer to and incorporate by reference the procedural history set forth in their pending Motion for Summary Judgment, Document No. 16 filed June 4, 2012, pages 11-13.

On remand, Plaintiff has disclosed a single expert, Dr. Pike, and proffered his single expert report, to sustain her burden of proving all liability issues and causation. A separate motion filed by Defendants seeks summary judgment. In this motion, Defendants demonstrate that Dr. Pike's causation opinions are inadmissible under Rule 702.

C. Smell Disorders

Smell dysfunction is a fairly common condition. It was previously assumed, based primarily on subjective survey evidence, that 1-2% of the population suffers from chronic smell disorders. Within the last decade, using objective functional testing and modern epidemiological methods, the medical and scientific community has come to a consensus that the problem is far more widespread. It is now generally believed that approximately 4-5% of the adult population has anosmia – a complete lack of ability to smell – and another 13-14% has hyposmia,

significantly reduced smell function.[1] It is generally accepted in the medical and scientific communities that the most common causes of persistent smell loss are upper respiratory infections, such as cold and flu, sino-nasal diseases such as rhinitis and sinusitis, and head trauma, and that a substantial percentage of cases are classified as idiopathic, meaning the cause is unknown to medical science. These etiologies are said to account for about 94% of all cases of chronic smell disturbance.[2] It is also well-established that the risk of smell loss increases steeply with age, and that adults over the age of 70 like Raub are at very high risk of naturally occurring smell loss.[3]

The nerves which sense and transmit smell are the olfactory epithelium, located in a small, sheltered patch of tissue ("OE" or smell tissue") tucked away in the remote, superior (upper) portion of the nose in each nostril near the midline of the eyes.[4]

D. The Controversy Surrounding Zicam Intranasal Cold Remedy Gel and Zicam® Litigation

In September 2003, an ENT in Colorado published a case report suggesting that the Nasal Gel caused several of his patients to lose their sense of smell. Dr. Bruce Jafek theorized that the active ingredient in the Nasal Gel, zinc gluconate, when applied intranasally, reached and damaged the smell tissue and that it was the Nasal Gel, rather than the cold for which people take Zicam, which caused their loss. Dr. Jafek promoted his theory on *Good Morning America* in February 2004, and a host of other media outlets. Not surprisingly, his revelation connecting a popular cold remedy product to a condition caused by the common cold that afflicts a substantial

[1]Report of Kevin Kip ("Kip Rpt") ¶¶ 39-46 (App. pp. 13-18). References in this Motion to "App." refer to the exhibits in the Appendix of Materials in Support of the Motion for Summary Judgment, Document No. 16-1.
[2] Kip Rpt ¶¶ 45-46, 95 (App. pp. 17-18, 345-46) Report of Marion J. Fedoruk ("Fedoruk Rpt") at 6, 21-22 (App. pp. 59, 74-75); Depo of Cameron Godfrey M.D. ("Godfrey Depo") at 16:11-17:16 (App. pp. 172-173); Mandy Scheibe, et al., *Intranasal Administration of Drugs*, Arch. Otol. Head & Neck Surg., 134(6): 643-646 (June 2008) (Supp. App. pp. 24-27) References in this Motion to "Supp. App." refer to the exhibits in the Supplemental Appendix of Materials in Support of the Motion to Exclude Testimony of Steven Pike, M.D.
[3] Kip Rpt ¶¶ 39, 41, 44., 95 (App. pp. 13-14,16-17, 45-46);. Fedoruk Rpt at 6, 17 (App. pp. 59, 70).
[4] Fedoruk Rpt at 6 (App. p. 59); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652, *18-19 (N.D. Ala. Nov. 7, 2006).

percentage of the population unleashed a tidal wave of publicity, internet attorney solicitations . . . and litigation.[5]

When the scientific foundations of Dr. Jafek's theory were examined more closely, they were discredited in a series of rulings excluding his testimony. In all, seven federal courts found Dr. Jafek's toxicity and/or causation opinions to lack a reliable foundation and excluded them under Rule 702. In addition, another federal judge barred his opinions concerning a competing intranasal zinc gluconate cold remedy, a decision affirmed by the Eighth Circuit. Other experts who sought to testify that the Nasal Gel can or did cause smell loss were also excluded. Thus, at the time Raub used ZCROM, and at the time she filed this suit, the Federal courts were unanimous in rejecting experts' claims that the Nasal Gel causes or caused smell loss as unsupported.[6]

The primary basis for exclusion of all this testimony was lack of any reliable evidence of target organ exposure – that the Nasal Gel reached the smell tissue. All experts agreed that to produce smell loss zinc gluconate had to reach the smell tissue, and had to do so in an amount (a dose) capable of causing sufficient damage to compromise smell function. But the characteristics of the product (a viscous gel), the manner of application (a nasal spray or swab designed to deposit the gel in the nasal vestibule or the lower nasal cavity), and the nasal anatomy (bony projections or "turbinates" which block access to the olfactory cleft at the roof of the nose where the smell tissue is located) made it extraordinarily unlikely that *any* of the Nasal Gel reached the smell tissue, let alone a toxic dose. The published nasal drug deposition and distribution literature, as well as a published article on the deposition and distribution of the

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[5] Kip Rpt ¶¶ 48, 54 (App. pp. 19, 23-25).

[6] *Hans v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96779 (W.D. Ky. Sept. 29, 2006); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652 (N.D. Ala. Nov. 7, 2006); *Benkwith v. Matrixx Initiatives, Inc.*, 467 F. Supp. 2d 1316 (M.D. Ala. Dec. 27, 2006); *O'Hanlon v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 65655 (C.D. Cal. Jan. 4, 2007); *Hilton v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 73264 (N.D. Tex. Feb. 20, 2007); *Salden v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 18552 (E.D. Mich. Mar. 16, 2007); *Wyatt v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 67986 (N.D. Ala. Mar. 30, 2007); *Lusch v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 72068 (D. Or. Sept. 25, 2007); *Rose v. Matrixx Initiatives, Inc.*, 2009 WL 902311 (W.D. Tenn. Mar. 31, 2009; *Evans v. Matrixx Initiatives, Inc.*, 2009 U.S. Dist. LEXIS 88224 (M.D. Fla. Feb. 18, 2009). *See also Polski v. Quigley Corp.*, 2007 U.S. Dist. LEXIS 66005 (D. Minn. Sept. 5, 2007), *aff'd* 538 F.3d 836 (8th Cir. 2008).

Nasal Gel, confirmed that a viscous gel like the Zicam Nasal Gel is not capable of reaching the olfactory cleft in any significant amount under conditions of ordinary use.[7]

Dr. Pike's report in the MDL took a different tact. He theorized that zinc ions leach out of the Nasal Gel in the lower nasal cavity and are transported by a phenomenon of "electro-osmotic diffusion" to the smell tissue at the olfactory cleft. The details and basis of this theory are discussed below. Despite the lack of any basis to apply that theory to ordinary use of the Nasal Gel, the MDL Court ruled that Dr. Pike's electro-osmosis theory was admissible.[8] Defendant's Motion for Reconsideration was denied. Because the District Court's ruling was interlocutory, it has not yet been reviewed.

E. Dr. Pike's Report

Dr. Pike's report in this case essentially takes his MDL general causation report concerning the Nasal Gel and extends it to ZCROM, then adds the *ipse dixit* that ZCROM use was the cause of Raub's smell loss. Because Dr. Pike's extrapolation from the Nasal Gel product to the Oral Mist ZCROM product is unjustified and unscientific, his general causation opinion lacks reliability and fit under Rule 702. And because his specific causation opinion (that Raub's smell loss was caused by her ZCROM use) is entirely unsupported by any scientific reasoning or evidence, it too lacks reliability and fit under Rule 702.

Most importantly, however, Dr. Pike's general causation opinion fails at the threshold because of the vast holes in, and lack of support for, his target organ exposure theory – the lack of any reliable basis for his assumption that there is *any* significant exposure of the OE to zinc ions following ordinary use (oral application) of ZCROM. The cornerstone of Dr. Pike's target organ exposure theory as to ZCROM is a theory of "electro-osmosis" delivery, stemming from a single study by Sceusa and Ehrlich ("Sceusa").[9]

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[7] Kip Rpt ¶¶63-65 (App. pp. 29-31).

[8] *In re: Zicam Cold Remedy Marketing, Sales Practices, & Prods. Liab. Litig*, 2011 U.S. Dist. LEXIS 20356, *17 (D. Ariz. Feb. 24, 2011).

[9] Nicholas A. Sceusa and Paul M.Ehrlich, *Proof of Electro-Osmotic Drug Delivery: A Prejudiced Clinical Trial, Delivering From Mouth to Nose*, DRUG DELIVERY TECH, 8(9):50-56 (October 2008) ("Sceusa Study") (Supp. App. pp. 14-20).

Sceusa was a "proof-of-concept" study. The concept investigated was whether he could deliver zinc ions from the mouth to the nose by *creating* an electrical gradient sufficient to overcome "all the opposing vectors, gravity, and mucociliary clearance." Sceusa hypothesized he could do this by using a specially formulated buffered lozenge containing zinc gluconate "to induce a lowering of the pH of the mouth with respect to the nose, and thereby *a relative reversal of charge between mouth and nose.*" "This trial is submitted as proof-of-concept that electro-osmotic delivery exists and can be induced by the dosage form."[10]

Sceusa observed that "[t]he natural electrical gradient lies in the same direction as gravity and the mucociliary clearance and aids the nose to clean itself." In other words, the natural electrical gradient based on normal physiological pH values is from the nose to the mouth. "The lozenge was designed to buffer the pH of the mouth at approximately pH 5.4," while the subjects noses "had an average nasal pH of 6.35." Thus, the pH differential "was consistently at [0.95] pH units in favor of transport to the nose from the mouth." "Inducing the pH change takes control of the corresponding electrical vector, allowing us to manipulate the directions of ionic flow and transport." Thus, "[t]he reversed gradient allows drug delivery to occur over the palate and into the nose from the mouth." Zinc content of the nasal mucus was measured at the nasopharynx, at the lowest part of the nasal cavity just below the posterior end of the inferior turbinate.[11] The experimental lozenge resulted in an increased zinc content of .95 micrograms per milliliter over baseline.[12] The study concluded that by manipulating the pH differential, drug delivery can be facilitated, theorizing that "a small difference in [the pH ratio] makes a large difference in delivery."[13]

Thus, assuming the validity of this unreplicated study, it means nothing more than that by creating a pH differential of .95 with the higher value in the nasal cavity, one can overcome the forces of mucociliary clearance (the flow of mucus secretions in the nose toward the

[10] *Id.* at 50 (Supp. App. p. 14).
[11] *Id.* at 54 (Supp. App. p. 18).
[12] *Id.* at 56 (Supp. App. p. 20).
[13] *Id.* at 59 (Supp. App. p. 23).

nasopharynx and down the throat) and gravity to deliver .95 micrograms per milliliter of zinc *to the nasopharynx at the bottom of the lower nasal cavity.*

Notwithstanding these limitations, the experimental nature of the study, and the experimental conditions necessary for delivery to the nasopharynx, Dr. Pike apparently draws from it the conclusion that "zinc lozenge experiments have shown that positively charged zinc ions migrate from the mouth to the nose and that zinc cations . . . can find their way to the olfactory mucosa even when they originate from a solid zinc lozenge that dissolves in the mouth."[14] He then overextends Sceusa even further: "By analogy, the already solubilized zinc gluconate and zinc acetate sprayed into the mouth releases toxic zinc cations that also migrate into the nose and find their way to the olfactory nasal mucosa."[15] And even further: "An established electro-osmotic gradient from the oral mucosa to the nasal mucosa more likely than not" produces toxic reaction at the OE in susceptible individuals.[16] And still further: "*Intranasal application*" of Zicam Nasal gel "results in distribution of zinc cations throughout the nasal mucosa."[17] The only source cited or discussed for any of these propositions is the Sceusa study, which supports *none* of them.

Without any basis for concluding that ordinary, real-world use of ZCROM reverses the natural electrical gradient from nose to mouth, and without conducting any calculations, tests, or models to test his hypothesis or apply it to the facts surrounding ZCROM use, Dr. Pike opines that such use produces migration of zinc cations not only to the nose, but to the OE at the very roof of the nasal cavity, and delivers an amount capable of producing permanent anosmia. Dr. Pike cites no evidence that ZCROM use reduces the pH in the mouth to less than that of the nose. Moreover, Dr. Pike has cited (and apparently knows of) no evidence that the pH of the lower nasal cavity is different than the upper nasal cavity near the OE, much less a substantial

[14] Report of Steven Pike, M.D. ("Pike Rpt") at 4 (App. p. 79).
[15] *Id.*
[16] *Id.* at 29 (App. p. 104).
[17] *Id.* at 9 (App. p. 84) (emphasis added).

difference of the type or magnitude experimentally created by Sceusa.[18] Further, Dr. Pike has not explained how much zinc he believes would make it to the OE under his theory. Finally, Dr. Pike has no idea how much of the OE, needs to be destroyed in order to produce any smell loss – much less the permanent and complete smell loss he opines Raub developed as a result of ZCROM use.[19] His general causation theory therefore fails at multiple steps in his chain of reasoning, and each failed step is dispositive.[20] Thus, Dr. Pike's general causation opinion is speculation, a classic untested and unsupported hypothesis lacking in any reasonable or reliable scientific foundation.

The sum total of Dr. Pike's specific causation "analysis" consists of part of a single concluding paragraph, on the 32nd and last page of his report, a literal afterthought. In the last two sentences of his report Dr. Pike simply concludes, without any analysis, that:

> I have showed a proximal temporal relationship between Doris Raub's use of [ZCROM] and injury to her olfactory nasal epithelium that was a substantial factor causing her anosmia and substantial taste impairment and her resulting severe morbidity.[21]

DISCUSSION AND APPLICATION OF RULE 702 TO DR. PIKE'S OPINION TESTIMONY

Under Texas product liability law, the plaintiff in a toxic exposure case must prove both general causation (that the exposure is capable of causing the subject disease in humans) and specific causation (that the plaintiff's exposure was the actual cause of the plaintiff's condition).[22] Scientific knowledge of the harmful level of exposure to the chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain a plaintiff's burden in a toxic tort case.[23] If an expert's causation opinion is not based on

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[18] *See* Depo. of Steven Pike M.D. in *In re Zicam Cold Remedy Marketing, Sales, & Prods. Liab. Litig.* at 66:18-67:2, 90:19-91:12 (hereafter cited as "Pike MDL Depo") (Supp. App. pp. 5-6, 8-9).
[19] *Id.* at 73:5-21, 109:11-111:10 (Supp. App. pp. 7, 10-12).
[20] *See Moore v. Ashland Chem. Co.*, 151 F.3d 269, 278 & n.10 (5th Cir. 1998) (*en banc*) ("Under *Daubert*, '*any* step that renders the analysis unreliable . . . renders the expert's testimony inadmissible.'") (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994) (emphasis in original).
[21] Pike Rpt at 32 (App. p. 107).
[22] *Easter v. Aventis Pasteur, Inc.*, 358 F. Supp. 2d 574, 575 (E.D. Tex. 2005); *see also Knight v. Kirby Inland Marine, Inc.*, 482 F.3d 347, 355 (5th Cir. 2007).
[23] *Curtis v. M & S Petroleum, Inc.*, 174 F.3d 661, 670 (5th Cir. 1999).

sufficient information of the level of the agent to which plaintiff was exposed, his methodology is not reliable, and his causation opinion is inadmissible.[24]

A. The Law Precludes Opinions Based On Junk Science

Rule 702 and *Daubert* direct District Courts to police the foundations of expert causation opinions in toxic tort cases like this one so that juries are not burdened with junk science as they sort out complex scientific issues, as "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it."[25] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Daubert requires the court to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable."[26] To do this, the court must determine whether the expert's opinion qualifies as "scientific knowledge,"[27] *i.e.*, whether it has a reasonable and reliable basis in the data and methodology, "and the court must exclude the opinion if it appears to be based on 'unsubstantiated generalizations, speculative hypotheses and subjective evaluation.'"[28] "'Scientific' implies a grounding in the methods and procedures of science," and "'knowledge' connotes more than subjective belief or unsupported speculation."[29] Rather, "knowledge" is that which is "accepted as truth on good grounds."[30] Accordingly, untested, unproven theories are inadmissible; to be admissible, an expert opinion must have a reliable basis in the knowledge and experience of the relevant discipline.[31] Overall, Rule 702 gatekeeping is designed to ensure that the

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[24] *Id.* at 671.
[25] *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 595 (1993).
[26] *Id.* at 589.
[27] *Moore.*, 151 F.3d at 275; *see also id.* at 278 (the court "must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist") (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316 (7th Cir. 1996)).
[28] *Cacciola v. Selco Balers, Inc.*, 127 F. Supp. 2d 175, 184 (E.D.N.Y. 2001).
[29] *Moore*, 151 F.3d at 275.
[30] *Daubert*, 509 U.S. at 590.
[31] *Id.* at 592.

expert has applied the same standards of scientific and intellectual rigor to his testimony in court as experts apply to their work in the field.[32]

The Supreme Court has identified a non-exhaustive list of factors that might be considered in evaluating whether the evidence is sufficiently reliable to be admitted: (1) whether the theory or technique has been and could be tested; (2) whether it has been subjected to peer review; (3) whether scientific standards and controls exist to govern the theory or technique's application or operation; (4) the known or potential error rate from the expert's methodology; and (5) the degree to which the technique or theory has been generally accepted in the scientific community.[33]

The Federal Rules Advisory Committee lays out a number of additional relevant factors in its explanation of the 2000 amendments to Rule 702:

> (1) Whether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying...
>
> (2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion...
>
> (3) Whether the expert has adequately accounted for obvious alternative explanations...[and]
>
> (4) Whether the expert is being as careful as he would be in his regular professional work outside his paid litigation consulting.[34]

The potential pitfalls identified by the Advisory Committee also appear in a list of "red flags" collected in a treatise on the admissibility of scientific testimony after *Daubert*.[35] As discussed below, Dr. Pike's proffered opinions do not withstand scrutiny under the factors set forth in *Daubert* and raise many of the "red flags" identified by the Advisory Committee. Although none

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[32] *Burleson v. Texas Dept. of Criminal Justice*, 393 F.3d 577, 584 (5th Cir. 2004); *Watkins v. Telsmith Inc.*, 121 F.3d 984, 990 (5th Cir. 1997).
[33] *Daubert*, 509 U.S. at 593-95; *Moore*, 151 F.3d at 275.
[34] Advisory Committee Notes, FED. R. EVID. 702 (citations and internal quotations omitted).
[35] *See* Steven A. Saltzburg, et al., FEDERAL RULES OF EVIDENCE MANUAL Sec. 702.02[7] (8th ed. 2002); *see also Downs v. Perstor Components, Inc.*, 126 F. Supp. 2d 1090, 1125-27 (E.D. Tenn. 1999), *aff'd* 2002 WL 22000 (6th Cir. Jan. 4, 2002) (approving use of the "red flags").

of these factors is dispositive alone, each weighs strongly against admissibility, and together they compel the exclusion of Dr. Pike's causation testimony.

As the Supreme Court recognized in *General Elec. Co. v. Joiner*,[36] the court may also exclude expert testimony where "there is simply too great an analytical gap between the data and the opinion proffered." The burden is on Raub to demonstrate that Dr. Pike's opinion testimony is sufficiently reliable and relevant to be admissible under Federal Rule of Evidence 702.[37] Here, Dr. Pike's general causation opinion is predicated on unwarranted extrapolations from an experimental study, and his specific causation opinion is nothing more than a naked conclusion bootstrapped from his general causation opinion. The chasm between the scientific data and principles, on the one hand, and Dr. Pike's conclusions, on the other, is just too great to justify its admission.

B. Dr. Pike's General Causation Opinion Is Unreliable Because There Is No Reliable Basis For His Threshold Opinion That Ordinary Use of ZCROM Results in Delivery of a Toxic Dose of Zinc to the Smell Tissue

1. Dr. Pike's Opinion That ZCROM Use Results in Target Organ Toxic Exposure Is Unreliable and Speculative Because There Are Excessive Analytical Gaps

As the courts have recognized, there is no reliable evidence of a *toxic* exposure, *i.e.*, exposure of the smell tissue to *too much* of the substance, if there is no reliable evidence of *any* exposure of the target organ to the substance.[38] The cited cases, and other Zicam cases, found there was no reasonable and reliable basis for a scientific conclusion that the Nasal Gel reaches the smell tissue, precluding any demonstration of general causation.

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[36] 522 U.S. 129, 146 (1997).

[37] *Moore*, 151 F.3d at 275.

[38] *See, e.g., Hilton v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 73264, *5-7 (N.D. Tex. Feb. 20, 2007); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652, *18, 34 (N.D. Ala. Nov. 7, 2006); *Lusch v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 72068, *13-14 (D. Or. Sept. 25, 2007). *See also Polski v. Quigley Corp.*, 538 F.3d 836, 840-841 (8th Cir. 2008) (same conclusion as to a competing zinc gluconate gel cold remedy); Fedoruk Rpt at 9 (App. p. 62) (scientific data demonstrating zinc ions can reach the smell tissue from use of the product is a requirement for establishing general causation; there is no reliable scientific evidence that zinc ions in ZCROM travel to the smell tissue).

Dr. Pike takes a different approach in attempting to satisfy this threshold toxicological requirement, focusing exclusively on the zinc ions which disassociate from the Nasal Gel (or here, the Oral Mist), and treating them as a separate entity from the gel or mist from which they originate. But this change of focus is unavailing, because he lacks any reliable scientific basis to conclude that zinc ions from the Oral Mist ingested through the mouth are transported from the mouth to the smell tissue at the roof of the upper nasal cavity.

Dr. Pike relies on a phenomenon called electro-osmotic diffusion, based on a single 2008 study (Sceusa). The study has never been replicated, but more importantly it simply does not support his opinion that ZCROM use results in delivery of any significant amount of zinc ions to the smell tissue. Rather, Dr. Pike's opinions based on the study are plagued with multiple analytical gaps.[39]

Sceusa posited that he could experimentally *create* an electrical gradient capable of transporting zinc ions *from the mouth to the nose* using a specially formulated zinc gluconate lozenge. To do so, he chemically lowered the pH in the mouth to 5.4, creating a pH differential of .95 less than the nose, and measured zinc delivery to the nasopharynx. Assuming the validity of the Sceusa study, as far as it went, it does not support Dr. Pike's opinion for several reasons.

The required pH differential is lacking. The cornerstone of Sceusa's experiment was the artificial creation of a substantial pH differential, with the mouth .95 pH lower than the nose. There is no evidence that ZCROM use creates an analogous pH differential/electrical gradient, either in magnitude or direction. The physiologic pH of the mouth is normally higher than that of the nasal cavity; Sceusa's experimental buffered lozenge created a relative reversal of the electrical gradient.[40] Accordingly, Dr. Pike has not shown and cannot show either the necessary pH differential, nor the necessary directional flow (mouth-to-nose), that Sceusa needed to overcome mucociliary clearance and gravity and transport zinc to the bottom of the lower nasal cavity. Simply put, the conditions that supposedly allowed Sceusa to deliver zinc from the

[39] *See* Fedoruk Rpt at 9 (App. p. 62).
[40] Sceusa Study at 50 (Supp. App. p. 14); Fedoruk Rpt at 9-11 (App. pp. 62-64).

mouth to the nasopharynx are not present with ZCROM use. Indeed, that Sceusa found it necessary to drastically artificially lower the pH of the mouth to reverse the relative charge in order to get zinc cations to the nasopharynx strongly suggests that no such delivery takes place when the pH is *not* experimentally altered – such as with ordinary use of ZCROM. Dr. Pike cannot, consistent with the scientific method, rely on those aspects of Sceusa which supposedly support his theory but ignore the limitations which do not fit his theory.[41] Pike's reliance on Sceusa is therefore scientifically misguided, invalid and unreliable.

Sceusa did not deliver zinc from the mouth to the smell tissue, nor suggest that he could do so. All Sceusa studied was that zinc ions (under experimental conditions) could be transported to the nasopharynx. That is where he measured the zinc. Nothing in Dr. Pike's report explains the mechanism for getting the zinc ions from the *floor* of the lower nasal cavity to the very top of the upper nasal cavity, where the smell tissue resides.[42] It is scientifically invalid to draw conclusions from a study not drawn by the authors – particularly when the study did not investigate, and therefore generated no data, on that point.[43]

Sceusa claims to have delivered zinc to the floor of the lower nasal cavity because the pH of the mouth was substantially lower than the pH of the nose. But Dr. Pike's report cites no evidence that there is *any* pH differential between the lower nasal cavity and the upper nasal cavity which would be even theoretically capable of continuing and completing the journey to the smell tissue.[44] This data vacuum and geographical distance combines to create a capacious analytical gap; Dr. Pike's *leap* from the Sceusa study to his opinion of delivery to the smell

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[41] *See Cano v. Everest Minerals Corp.*, 362 F.Supp.2d 814, 850-53 (W.D. Tex. 2005) (not reliable methodology to rely on favorable aspects of scientific literature and ignore or unreasonably reject aspects which fail to support theory).

[42] Fedoruk Rpt at 11 (App. p. 64).

[43] *Joiner*, 522 U.S. at 145; *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1238, 1245-1247 (11th Cir. 2005); *In re Accutane Prods. Liab. Litig.*, 511 F. Supp. 2d 1288, 1290-1291 (M.D. Fla. 2007); *Kelley v. American Heyer-Schulte Corp.*, 957 F. Supp. 873, 878-879 (W.D. Tex. 1997). *See Knight*, 482 F.3d at 355 (expert's opinion properly excluded where scientific studies relied on did not support the conclusion, creating an analytical gap).

[44] Dr. Pike has previously testified that he is not aware of any pH differential between the lower and upper nasal cavities. *See* Pike MDL Depo. at 66:18-67:2, 90:19-91:12 (Supp. App. pp. 5-6, 8-9).

tissue is unfounded, unscientific and speculative. One cannot "bridge" the analytical gap with a leap of faith. That would be the antithesis of science.

Sceusa does not support a conclusion that a *toxic dose* of zinc cations travels through electro-osmosis to the smell tissue. Even assuming Dr. Pike had tested his theory and shown that *some* zinc ions find their way to the smell tissue, to support a general causation opinion that exposure to ZCROM is capable of producing permanent anosmia, the expert must have a reliable basis for concluding that a *toxic dose* – a dose capable of causing permanent anosmia – is delivered to the target organ, the smell tissue.[45]

Dr. Pike's report ignores this question. While he claims that zinc cations at low concentrations can kill a cell, he does not do any calculations, modeling, or testing, or cite to any, which reasonably shows or estimates the amount of zinc cations which would survive the journey to the smell tissue, nor the surface area or amount/proportion of olfactory receptors that would be compromised if it gets there. Assuming enough arrives there to damage *some* olfactory neurons, how many will it destroy and how many need to be destroyed to produce (1) any measurable effect on smell function, and (2) the drastic affect he claims Raub experienced – complete and permanent smell loss? Dr. Pike ignores this question of dose-response, how much exposure is necessary to cause the alleged harm in living humans, despite the fact that the OE contains numerous neurons and the neurons ordinarily regenerate even after being damaged.[46]

> When analyzing an expert's methodology in toxic tort cases, the court should pay careful attention to the expert's testimony about the dose-response relationship. ... The expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology.[47]

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[45] *See, e.g., Allen v. Pennsylvania Engineering* Corp., 102 F.3d 194, 199 (5th Cir. 1996); *Curtis.*, 174 F.3d at 670-671; *Moore*, 151 F.3d at 278; *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1106-1108 (8th Cir. 1996); *Mitchell v. Gencorp.*, 165 F.3d 778, 781 (10th Cir. 1999); *McClain*, 401 F.3d at 1240-1242.

[46] Fedoruk Rpt at 6 (App. p. 59).

[47] *McClain*, 401 F.3d at 1241-1242 (citation omitted). The court went on to describe dose-response relationship as the foremost "principle" of toxicology that a court should consider in 'any attempt to establish whether a chemical exposure was causally related to a specific adverse effect or disease in an individual.'" *Id.* at 1242 (citation omitted). *See also id.* at 1240, 1241, 1242 n.6 (dose-response relationship is "the hallmark of the science of toxic torts", "the basic methodology that scientists use to determine causation" and "a key element of reliability in toxic tort cases"). Of course, because there is no reliable scientific evidence that *any* significant amount of zinc from ZCROM reaches the OE under conditions of ordinary use, the dose-response requirement fails at the threshold.

There is a good reason why Dr. Pike has ignored these critical dose-response questions: we know from his testimony as to the Nasal Gel that he cannot answer them.[48]

Given the multiple analytical gaps between the Sceusa study and Dr. Pike's opinion that ZCROM use delivers a toxic dose of zinc cations to the smell tissue through a process of electro-osmosis, his opinion is inherently speculative and demonstrably unreliable. It is not based on sufficient facts or data, and Dr. Pike's laps of faith are decidedly *not* capable of bridging the analytical gaps. Rather, they cogently demonstrate that Dr. Pike's analysis is far from the reliable application of reliable scientific methods contemplated and required by Rule 702.[49]

2. The Rule 702 Reliability Factors Confirm That Dr. Pike's General Causation Opinion Testimony Is Unreliable and Inadmissible.

The reliability factors set forth in *Daubert* and Rule 702 all expose the lack of reliability to Dr. Pike's general causation opinion.

Dr. Pike's theory has not been tested. There are no calculations, experiments, studies, or tests which demonstrate, even theoretically, that application of an oral mist, or *any* oral delivery form of a zinc compound, results in transport of any toxicologically significant level of zinc cations to the smell tissue, or even the upper nasal cavity. An untested hypothesis is nothing more than speculation.[50]

Dr. Pike's theory has not been peer-reviewed or published. The theory has never been subjected to the scrutiny of the scientific community; it's entire audience has been the lawyers and the Court involved in Zicam litigation.[51]

There are no standards or controls which govern the application or operation of Dr. Pike's theory. It is an entirely subjective, and therefore standardless, opinion, entirely unproven and unvalidated.[52]

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[48] Dr. Pike has testified that he does not know how much of the OE needs to be compromised in order to produce any smell loss, or complete smell loss. Pike MDL Depo at 73:5-21, 109:11-111:10 (Supp. App. pp. 7, 10-12).
[49] *See Knight*, 482 F.3d at 355.
[50] *See Rosen*,78 F.3d at 319 ("The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.").
[51] *Daubert*, 509 U.S. at 593; *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

Similarly, there is no known or quantifiable error rate applicable to Dr. Pike's subjective, untested opinion. Given its abject subjectivity, however, the potential for error is unlimited.

Dr. Pike's theory of electro-osmotic delivery is not generally accepted in the scientific community. Even as far as it goes, Sceusa's study was a "proof-of-concept" which has never been replicated. Dr. Pike points to no source, let alone a substantial minority of the scientific community, which accepts it as a true *real world* mechanism of delivery of cations to the upper nasal cavity.

Dr. Pike is not testifying about matters growing naturally and directly out of research conducted independent of litigation. Rather, his opinion of electro-osmotic delivery was developed expressly to support a general causation opinion in the MDL and imported here and applied to ZCROM for this case.[53]

Dr. Pike has unjustifiably extrapolated from a *questionable* premise to an unfounded conclusion. Sceusa's premise of delivery to the nasopharynx is not *established*, as it is not replicated, but for the reasons discussed above, Dr. Pike's extrapolation from it to conclude that ZCROM use causes delivery to the smell tissue is unsupported, unreasonable, and unreliable. Likewise, he further extrapolates from this unsupported conclusion that *some* zinc cations are delivered to the smell tissue to the unsupported conclusion that a toxic dose (i.e., a dose capable of causing permanent anosmia) gets there – with no support apart from his own subjective assumption.

Dr. Pike has not accounted for obvious alternative theories. For example, that the relative pH values of the oral and nasal cavities under conditions of ordinary use either *inhibit* electro-osmotic transport to the nose, are *neutral* (*i.e.*, have no effect), or are insufficient to

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[52] *See Moore*, 151 F.3d at 275 ("scientific knowledge" must be more than subjective belief or unsupported speculation). *See also Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 424 (5th Cir. 1987); *Nadell v. Las Vegas Metro Police Dept.*, 268 F.3d 924, 927-28 (9th Cir. 2001) (subjectivity of interpretation of testing rendered testimony unreliable); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1106-07 (7th Cir. 1994) (expert testimony based on visual observation was overly subjective methodology and excluded).

[53] *See In re Air Crash Disaster at New Orleans*, 795 F.2d 1230, 1234 (5th Cir. 1986) (whether evidence was developed for litigation purposes is an important factor in determining admissibility).

produce any significant delivery all the way to the smell tissue. He has performed no calculations, analysis, modeling, or testing to determine what the impact of any electro-osmotic input might be. Instead, he has simply assumed his conclusion, the inference which favors his client, without analyzing whether it in fact has any scientific basis.[54]

Dr. Pike's litigation analysis fails to exercise the level of care and rigor ordinarily practiced by a toxicologist conducting a professional risk assessment or causal investigation. This is virtually self-evident from the above-described deviations from reliable scientific methodology and the conclusions drawn without reliable scientific support. It is hard to imagine that any licensed medical toxicologist would present as a scientific fact (rather than a hypothesis, or possibility) a conclusion unsupported by any direct research or based entirely on unwarranted extrapolations and leaps of faith from, at best, marginally relevant existing research such as the Sceusa study.

Some of these factors apply more than others, but all of them expose the analytical gaps and fundamental methodological and foundational flaws that render Dr. Pike's general causation opinion speculative and unreliable. Because his opinion is not based on sufficient facts or data, and is not the product of a reliable application of reliable scientific methods, it is inadmissible under Rule 702.

C. Dr. Pike's Specific Causation Opinion, That ZCROM Use Was the Cause of Raub's Permanent Anosmia, Is Unreliable and Inadmissible

Dr. Pike is Raub's sole expert. He therefore is required to carry the burden of proving not only that ZCROM is capable of causing permanent anosmia under conditions of ordinary use, and therefore is a potential cause of Raub's alleged permanent anosmia (general causation), but also specific causation, that ZCROM, and not any other potential cause, actually caused her permanent anosmia. "To establish specific causation (that a product was the cause-in-fact of

[54] *See Sutherland*, 2006 U.S. Dist. LEXIS 96652, at *25, 34.

plaintiff's injury), an expert must demonstrate a 'specific train of medical evidence' connecting the illness to the product."[55]

1. Dr. Pike's Specific Causation Opinion Fails Along With His Predicate General Causation Opinion

A reliable and admissible conclusion that ZCROM use could have caused Raub's alleged permanent anosmia is a prerequisite to a reliable and admissible opinion that it actually did.[56] Because Dr. Pike's general causation opinion is unreliable and inadmissible, his specific causation fails for this reason alone.

2. Dr. Pike's Specific Causation Opinion Fails Because It Is Devoid of Reasoning and Data – It Is a Mere *Ipse Dixit*

Perhaps the most fundamental teaching of *Daubert* and the core indicia of reliability of expert opinion under Rule 702 is the premise that expert opinion testimony must be supported by more than the naked authority of the expert. The opinion must be *demonstrably* based on sufficient facts or data, and it must be *demonstrably* the product of reliable scientific principles and methods reasonably and reliably applied to the facts of the case. "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process."[57] Accordingly, in this Circuit, the expert "must demonstrate a 'specific train of medical evidence' connecting the illness to the product."[58]

Dr. Pike's report briefly discusses Raub's history and the documents reviewed, then spends about 30 pages purporting to demonstrate general causation (almost all of that discussion focusing on the Nasal Gel, a dissimilar product that Raub did not use). Then, on page 32, in the conclusion section – and indeed, in the final two sentences of the final paragraph of the report – Dr. Pike turns to specific causation. Without any explanation or discussion of how the circumstances of Raub's use and exposure, the manifestation of her injury, or any relevant

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[55] *Newton v. Roche Laboratories, Inc.*, 243 F. Supp. 2d 672, 682 (W.D. Tex. 2002) (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999)).
[56] *Knight*, 482 F.3d at 351.
[57] *Rosen*, 78 F.3d at 319. *See also Viterbo*, 826 F.2d at 424 ("Without more than credentials and a subjective opinion, an expert's testimony that "it is so" is not admissible.").
[58] *Newton*, 243 F. Supp. 2d at 682 (quoting *Black*, 171 F.3d 3 at 314).

aspects of her medical history support such an opinion, Dr. Pike suddenly declaims that ZCROM was the cause of Raub's permanent anosmia. By doing so, Dr. Pike exposes his opinion for precisely what it is, a *fait accompli* fulfilling his litigation assignment of delivering a favorable causation conclusion for the Plaintiff.

As the Supreme Court held in *Joiner*, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[59] *A fortiori* exclusion is warranted when the expert proffers no connection between any data and his opinion, as here.

It is inherent in the taxonomy of general and specific causation that just because something *can* cause a medical condition does not mean that it did. Particularly here, where Raub had several well-established causes of permanent smell loss in her medical profile – the common cold, her advanced age, and her nasal-sinus disease – it is incumbent upon the expert to attempt to rule out alternative explanations for Raub's conditions.[60] Dr. Pike's *ipse dixit* is tantamount to a tacit concession that he cannot; in any event, it does not come close to satisfying the requirement of a reasonable explanation and a "specific train of medical evidence connecting the illness to the product."

Indeed, the comments to Rule 702 specifically speak to the requirement of ruling out alternative explanations as a recognized indicia of reliability *vel non*:

> Courts both before and after *Daubert* have found other factors relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact. These factors include: ...(3) whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N. R.R. Co.*, 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff's condition). *Compare Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert).[61]

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[59] *Joiner*, 522 U.S. at 146.

[60] Godfrey Depo at 36:9-24, 37:19-21, 38:3-5 (App. pp. 185-187)

[61] Advisory Committee Notes, FED. R. EVID. 702. *See also* Steven A. Saltzburg, et al., *Federal Rules of Evidence Manual*, *supra*, §702.02[7]; Michael D. Green, *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON

There is no question on this record that this reasonable ruling out process has not been undertaken, much less accomplished. Raub had her cold before and after she used ZCROM in February 2009, and she first noticed long after she stopped using ZCROM that her senses of smell and taste were compromised. Dr. Pike cites no evidence or reason to select ZCROM over the cold as the cause of Raub's smell loss, and thus simply adopts, without basis or explanation, a questionable (at best) theorized cause over a common and well-established cause that obviously fits Raub's manifestation scenario. The rejection of simpler, more apparent and generally accepted explanations in favor of a novel and complex theory violates the rule of parsimony, also known as "Occam's Razor." Courts have branded such obviously biased, subjective and opaque specific causation conclusions as unreliable and inadmissible for this reason.[62]

Similarly, Dr. Pike fails to even attempt to rule out Raub's age – indeed, his report never even mentions Raub's date of birth or age, much less explain why it can be reasonably ruled out or subordinated. And though Dr. Godfrey and Dr. Palomo both cited Raub's rhinitis as a possible cause, it gets no mention from Dr. Pike.[63] Thus, Dr. Pike has merely bootstrapped his general causation opinion into a specific causation conclusion – it can cause, therefore it did cause. It does not take a citation to a learned treatise or text to recognize that this is not a reasonable and reliable scientific approach to questions of cause-and-effect. This is not reliable science, but unabashed advocacy.

SCIENTIFIC EVIDENCE (Fed. Jud. Center ed. Lexis Pub'g 2000), at 369-73, 378 (discussing the importance of ruling out rigorously the possibility of confounding factors); *In re Propulsid Prods. Liab. Litig.*, 261 F.Supp.2d 603, 618 (E.D. La. 2003) (experts' testimony held unreliable and inadmissible in part because of inability to rule out other explanations for plaintiff's alleged injuries).

[62] *See Kelley*, 957 F.Supp. at 882 (excluding specific causation opinion in part because the expert's "reasoning fails the test of parsimony"); *see also Justiss Oil Co. v. Kerr-McGee Refining Corp.*, 75 F.3d 1057, 1060-61 & n.10 (5th Cir. 1996) (approving use of Occam's Razor in analyzing causation evidence and listing cases that apply the rule); *Cano*, 362 F. Supp. 2d at 837-38 (where expert failed to scientifically rule out known causes and selected a cause that is not generally accepted as established, opinion was unreliable and inadmissible).

[63] Godfrey Depo at 36:9-11 (App. p. 185).

Dr. Pike's failure to properly account for other well-established causes of plaintiff's loss of smell renders his conclusions unreliable and speculative.[64] In *Viterbo*, the Fifth Circuit observed:

> We do not hold, of course, that admissibility of an expert opinion depends upon the expert disproving or discrediting every possible cause other than the one espoused by him. Here, however, Dr. Johnson has admitted that Viterbo's symptoms could have numerous causes and, without support save Viterbo's oral history, simply picks the cause that is most advantageous to Viterbo's claim. Indeed, Dr. Johnson's testimony is no more than Viterbo's testimony dressed up and sanctified as the opinion of an expert. Without more than credentials and a subjective opinion, an expert's testimony that "it is so" is not admissible.[[65]].

It should be noted that Dr. Pike's terse mention of having "showed a proximal temporal relationship between" Raub's use and her injury proves nothing more than his degree of bias. Again, Raub used ZCROM during her extended cold, and stopped using it because it did not seem to be helping. Her cold persisted for a period of time thereafter, and then she later noticed her sensory loss.[66] Describing this as a "proximal temporal relationship" with her ZCROM use but ignoring the relationship with the cold merely highlights that Dr. Pike has "simply pick[ed] the cause most favorable to [Raub's] claim."[67] Moreover, "the Fifth Circuit has rejected expert testimony that relies 'substantially on the temporal proximity between exposure and symptoms.'"[68]

Dr. Pike's specific causation analysis is speculative, biased and unsupported in medicine and science. His complete failure to apply scientific reasoning rather than subjective opinion and *ipse dixit*, independently renders his testimony unreliable, irrelevant and inadmissible. For these reasons, his opinions should be excluded.

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[64] *See Viterbo,* 826 F.2d at 423 (excluding testimony of physician that defendant caused plaintiff's illness where physician relied on a medical history that omitted important information).
[65] 826 F.2d at 424. *See also Easter*, 358 F. Supp. 2d at576 (failure to take serious account of other potential causes undermines reliability).
[66] *See* Raub Dep. pp. 39:2-4, 58:21-60:24, 63:12-16, 64:11-12, 71:15-72:7, 73:1-2, 74:17-75:19, 80:6-11, 81:2-6, 10-17 (App. pp. 201, 204-206, 208-209, 211, 213-215,217- 218).
[67] *See* Fedoruk Rpt at 16, 21 (App. pp. 69, 74); Kip Rpt ¶ 96 (App. p. 46).
[68] *Newton*, 243 F. Supp. 2d at 683 (quoting *Moore*, 151 F. 3d at 278); *see also Black*, 171 F.3d at 313 (rejecting reliance on temporal proximity as "not an exercise in scientific logic but in fallacy of post-hoc propter-hoc reasoning, which is as unacceptable in science as in law").

D. Dr. Pike's General and Specific Causation Opinions Also Lack Fit Under Rule 702.

Rule 702 carries its own refined definition of relevance, requiring that expert testimony "assist the trier of fact." Scientific expert testimony is helpful and relevant if it bears a valid scientific connection to the issues addressed, which are in turn measured by the substantive requirements of state tort law.

In a case for personal injury due to toxic exposure, Texas law imposes certain minimum requirements to satisfy the causation element.[69] Specifically, plaintiff must produce two independent epidemiologic studies showing a statistically significant doubling of the risk of injury for individuals taking the drug in question.[70] Controlled studies demonstrating the requisite increased risk above background rate are peculiarly important here, because anecdotal reports such as spontaneous adverse event reports regarding ZCROM are "confounded by indication" – the very condition that ZCROM is used to treat, the cold, is also the most common cause of permanent anosmia.[71] As noted, the temporal relationship between ZCROM use and smell loss overlaps with the relationship between the cold and smell loss.

Dr. Pike's opinion testimony does not assist adjudication of causation because it fails to meet the minimum requirements of *Havner*. Not only is there no epidemiological study supporting his opinion, he completely ignores the fact that multiple randomized double-blind placebo controlled clinical studies – the gold standard for epidemiology study[72] – have been conducted with various forms of oral zinc and failed to produce any reports of smell loss.[73]

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[69] *See E.I. DuPont de Nemours & Co. v. Robinson*, 923 S.W.2d 549 (Tex. 1995); *Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997); *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256 (Tex. 2011).
[70] *Garza*, at 265-267.
[71] Kip Rpt at ¶33 (App. p. 11). *See Chambers v. Exxon Corp.*, 81 F. Supp. 2d 661, 664 (M.D. La. 2000) (when the disease occurs in the general population without the exposure, epidemiological evidence is necessary to prove the disease is caused by the exposure), *aff'd* 247 F.3d 240 (5th Cir. 2001); *Cf. Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 868 (7th Cir. 2010) (when causation is confounded by indication, "determining the direction of causation is difficult at best").
[72] Kip Rpt ¶ 45 (App. p. 17).
[73] Fedoruk Rpt at 12-14 (App. pp. 65-67).

Failing to address scientific evidence inconsistent with the expert's opinion is another significant indicia of unreliability.[74]

Dr. Pike does purport to analyze relative risk of smell loss from ZCROM, using an FDA spontaneous adverse event reporting database, but this is "relative" to other products, not relative to the unexposed background rate. It is unreliable and insufficient for several reasons: (1) it is a single, non-replicated study, and *Garza* requires two studies; (2) it is not a "study", nor is it well-designed; it is a proportional reporting rate analysis comparing the number of reports submitted to FDA about various drugs, an analysis hopelessly confounded by publicity and litigation bias, and it does not compare relative risk between exposed and unexposed groups; and (3) it is based on spontaneous reports, which are notoriously unreliable for proving causation.[75] For similar reasons, courts have rejected both proportional reporting rate analyses and other evidence based on collections of spontaneous anecdotal reports.[76] Accordingly, Dr. Pike's general causation opinion lacks fit under Texas law and Rule 702.

Finally, Dr. Pike's specific causation opinion likewise lacks fit. An ipse dixit opinion, which merely tells the jury what it should decide without explaining why, does not advance the jury's fact-finding mission.[77] Dr. Pike's opinion tells the jury not a thing about how to sort through the potential causes in a reasoned way to determine actual cause.

For all these reasons, Dr. Pike's causation opinions lack fit.

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[74] *In re Bausch & Lomb Contact Lens Solution Prods.Liab. Litig.*, 2009 U.S. Dist. LEXIS 83849, *43-44 (D.S.C. Aug. 26, 2009); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 426 (S.D.N.Y. 2005).
[75] Kip Rpt at ¶¶ 34, 37, 53-54, 73-80 (App. pp. 11-12, 23-26, 33-38); Fedoruk Rpt at 16-17 (App. pp. 69-70).
[76] *See In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 807-808 (N.D. Ohio 2004); *McClain*, 401 F.3d at 1250.
[77] *United States v. Frazier*, 387 F.3d 1244, 1262-1263 (11th Cir. 2004); *In re Mentor Corp. ObTape TransObdurator Sling Prods. Liab. Litig.*, 2010 WL 1727828, *7, 23 (M.D. Ga. Apr. 27, 2010).

CONCLUSION

Federal Rule of Evidence 702 precludes the jury from being misled or fed an expert's speculation in the guise of scientific conclusion. Dr. Pike's opinions are, at best, untested hypotheses – naked speculation – and in reality, litigation-driven ipse dixits. They lack reliability and fit under Rule 702. For these reasons, Dr. Pike's causation testimony must be excluded.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing Motion to Exclude Testimony of Steven Pike, M.D. has been forwarded to all counsel of record via the Court's electronic filing system and/or by placing same in the U.S. Mail, postage prepaid and properly addressed on this 19th day of July, 2012.

By: /s/ Kealy C. Sehic
Kealy C. Sehic